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Abstract

The high cost of prescription drugs in the United States is a problem that has engendered much political attention. One proposed solution to the prescription drug problem is to permit reimportation of U.S.-made drug products, allowing Americans to take advantage of products sold at lower prices abroad. In 2000, the United States passed such a measure known as the Medicine Equity and Drug Safety Act (“MEDSA”), which, if implemented, would have overturned a decade-long ban on the reimportation of pharmaceuticals without the consent of the manufacturer. Though supported by many consumer advocates and politicians, MEDSA would have had tenuous affect on drug prices and posed unnecessary risks to consumer safety. Reimportation’s theoretic results of eliminating geographic price discrimination would have detrimental results for society as a whole by reducing the incentive for drug manufacturers to innovate. Furthermore, a global pricing system for pharmaceuticals may create severe consumer losses, especially in developing countries. Lastly, reimportation of patented goods may be subject to legal challenge under current construction of the exhaustion of rights principle. Rather than considering reimportation, the government should implement a policy that provides lower-cost drugs to those who need them the most, the uninsured elderly. A policy of price discounts for uninsured elderly would improve the prescription drug situation without threatening the incentives for pharmaceutical innovation, and would lead to greater social benefits overall.

Introduction

The increasing cost of patented pharmaceuticals is an explosive issue that has captured the attention of the elderly community, consumer advocates, the pharmaceutical industry and lawmakers in recent years. In the United States, the outcry against high prescription drug prices is fueled by the fact that many of such products are sold in other countries far more cheaply than at home. One proposed solution to the prescription drug problem is to permit reimportation of U.S.-made drug products, allowing Americans to take advantage of products sold at lower prices abroad. In 2000, the United States passed such a measure known as the Medicine Equity and Drug Safety Act (“MEDSA”),¹ which, if implemented, would have overturned a decade-long ban on the reimportation of pharmaceuticals without the consent of the manufacturer. Though the Secretary of Health and Human Services (“HHS”) has refused to implement MEDSA on public safety grounds, the issue of reimportation as a way to combat the high cost of prescription drugs remains hotly debated. Proponents of reimportation argue that it is a means by which consumers can obtain the same products for the cheapest price. Those opposed to reimportation of drugs eschew concerns about the safety of such products. The heart of the matter, though not as frequently discussed by politicians, is the proper role of intellectual property in the global pharmaceutical market.

This article explores the reimportation controversy and the national and international implications of a U.S. pharmaceutical reimportation policy. Part I describes the United States’ original decision to ban reimportation and how reimportation emerged recently on the U.S. political scene as a possible solution to the high cost of prescription drugs. Part II provides a background on intellectual property theory and parallel imports, the broader category of trademarked, copyrighted and patented goods that are imported without the permission of the authorized manufacturer, with a focus on the pharmaceutical industry. Part III describes the domestic and international legal treatment parallel imports, noting that recent judicial developments cast doubt upon the legality of the reimportation of patented goods into the United States. Part IV examines implications of a reimportation policy on the domestic and global drug market, concluding that not only will reimportation detrimentally affect the incentives for innovation in the pharmaceutical industry, but will potentially lead to greater consumer losses, especially in developing countries. Part V discusses various alternative solutions to the prescription drug problem, and proposes price discounts for seniors as a way of increasing access to drugs without curbing incentives for pharmaceutical innovation.

I.

Pharmaceutical Reimportation in the United States

Reimportation has only recently emerged in the spotlight as politicians have confronted the increasing frustration of the American public with the cost prescription drugs. The following sections will describe the United States’ historical approach of banning reimportation for pharmaceutical products and how reimportation came about as a possible solution to the high cost of prescription drugs.

¹Pub. L. No. 106-387 § 745, 114 Stat. 1549 (codified at 21 U.S.C. § 384 (2000)) [hereinafter MEDSA].

A.

The PDMA

In the United States, the reimportation of drugs by entities other than the original manufacturer is prohibited under the Prescription Drug Marketing Act of 1987 (“PDMA”).² The purpose of the PDMA is to control the distribution of prescription drugs in order to minimize the risk that consumers received “mislabelled, subpotent, adulterated, expired, or counterfeit pharmaceuticals.”³ The PDMA limits the following channels of distribution: 1) the reimportation of drugs, 2) the resale of drugs purchased by health care entities, 3) the distribution of drug samples, and 4) the wholesale distribution of drugs interstate.⁴

At the time of the PDMA’s passage, lawmakers focused primarily on consumer safety and protection. Congress presented findings that reimported drugs posed a risk to the American public because in the process of foreign shipping and handling, drugs could become subpotent or adulterated.⁵ Congress further found that a ready market for parallel imports allowed a cover for fraudulent practices and made the importation of counterfeit drugs easier.⁶

The PDMA provides that “no [prescription drug] which is manufactured in a State and exported may be imported into the United States unless the drug is imported by the person who manufactured the drug.”⁷ An exception is made for the customary practice of manufacturers to recall their own drugs.⁸ The PDMA also allows an exception for the Secretary of Health and Human Services to authorize reimportation in emergency situations.⁹

B.

The Rising Costs of Prescription Drugs

The arguments for allowing reimportation primarily come from consumer and elderly advocacy groups decrying the high cost of prescription drugs in the United States. Because Medicare does not cover outpatient prescription drug use,¹⁰ the financial burden on consumers can be large. In 2000, HHS issued a study at

²Pub. L. No. 100-293, 102 Stat. 95 (codified at 21 U.S.C. § 381(d) (2000)) [hereinafter PDMA]; see also William Davis, *The Medicine Equity and Drug Safety Act of 2000: Releasing Gray Market Pharmaceuticals*, TUL. J. COMP. & INT’L. L., 483, 485 (2001). In 1999, manufacturers reimported over \$13 billion dollars worth of drugs back to the United States, largely from the United Kingdom and Germany. Michael D. Dalzell, *Prescription Drug Reimportation: Panacea or Problem?*, MANAGED CARE, Dec. 2000, available at <http://www.managedcaremag.com/archives/0012/0012.reimport.html>.

³S. REP. NO. 100-303, at 1 (1988).

⁴*Id.* at 1.

⁵PDMA, *supra* note 2, at § 2(4).

⁶*Id.* at § 2(5).

⁷*Id.* at § 3.

⁸S. REP. NO. 100-303, at 3 (1988).

⁹PDMA, *supra* note 2, § 3.

¹⁰HHS, *PRESCRIPTION DRUG COVERAGE, SPENDING, UTILIZATION, AND PRICES 1* (2000), available at <http://aspe.hhs.gov/health/reports/drugstudy/>. There are certain exceptions for chemotherapy and anti-transplant rejection drugs. *Id.*

the request of President Clinton that surveyed pharmaceutical pricing and spending for groups with and without prescription drug coverage.¹¹ The study reported that in 1996, nearly a third of Medicare recipients did not have prescription drug coverage for at least one month, and 47% of beneficiaries lacked prescription drug coverage at some point during the year.¹² Furthermore, Medicare recipients without another source of prescription drug coverage spent more than twice the portion of their incomes on prescription drugs than those with coverage.¹³ For the 20% of beneficiaries with the highest drug spending, the difference in percent of income spent on prescription drugs for those with and without coverage was 2.6% and 8.1%, respectively.¹⁴ Of some significance is the fact that within the group of uncovered high prescription drug spenders, those persons below the poverty line spent 27.8% of their incomes on prescription drugs in 1996.¹⁵ The study also found that 16.4% of those without prescription drug coverage did not purchase needed medicines in 1997 due to their high costs; for those at and near poverty levels, the percentage was greater than 20%.¹⁶ Those without prescription drug coverage were also often prescribed different types of drugs from those with coverage.¹⁷

The HHS study found that overall spending on prescription drugs has risen dramatically.¹⁸ In 1990, U.S. prescription drug expenditures were \$37.7 million.¹⁹ By 1998, the figure was \$90.6 million, with the greatest increase occurring in the years immediately proceeding.²⁰ As a proportion of overall health care costs, prescription drugs rose from 5.4 % to 7.9% between 1990 and 1998.²¹ Though there are many possible explanations for the significant rise of prescription drug costs, including the substitution of drug therapies for other types of in-patient treatments,²² they do not diminish the increasing impact on those without prescription drug coverage.

The increasing cost of prescription drugs has engendered deep frustration from the public, which has demanded that the government address the problem. Political pressure for action is intense; in the words of one commentator “the cost of prescription drugs was the leading issue on every candidate’s lips” in the 2000 elections.²³ Though the Clinton Administration proposed in 1999 to include a prescription drug benefit in Medicare, Congress could not agree to such a plan.²⁴ The clash between Republicans, who wanted benefits through private insurers, and Democrats, who wanted a program incorporated into Medicare, resulted in an impasse on any prescription drug benefit plan.²⁵ Instead, Congress passed MEDSA, discussed below.

States are also beginning to take measures to alleviate medicine costs for their citizens. As of this writing,

¹¹*Id.* at 2.

¹²*Id.* at 21 tbl.1-1, 23 fig.1-1. Thirty-nine million Americans are currently Medicare beneficiaries, *See* Centers for Medicare and Medicaid Services, *Medicare Basics*, at <http://www.medicare.gov/Basics/Overview.asp>. Medicare offers health insurance to the U.S. elderly population over 65. *Id.*

¹³HHS, PRESCRIPTION DRUG COVERAGE, SPENDING, UTILIZATION, AND PRICES, *supra* note 10, at 70 tbl.2-19. For those under 65, the average expenditure for prescriptions drugs is.4% of income. *Id.* at 77 tbl.2-25.

¹⁴*Id.* at 70 tbl.2-19.

¹⁵*Id.* at 70 tbl.2-19.

¹⁶*Id.* at 82 tbl.2-27, 2-28. This figure applies to persons with incomes 100-150% times the poverty level without Medicaid coverage. *Id.*

¹⁷*Id.* at 82 - 83, 118 tbl.3-4.

¹⁸*Id.* at 83.

¹⁹*Id.* at 85 tbl.2-29.

²⁰*Id.* The dollar amounts are in nominal terms and therefore reflect inflation. *Id.* at 84. Controlling for inflation, however, the increase in amount spent on drugs has been significant. *Id.* at 84 fig.2-14.

²¹*Id.* at 85 tbl.2-29.

²²*Id.* at 85.

²³Spencer Rich, *Politics, As Usual, Rules Health Agenda*, 32 NAT. JOURNAL 3968 (2000).

²⁴Catherine Cowan, *Mixing Politics and Prescriptions; Maine Has Passed, and Other States Considering, a Law Permitting Prescription Drug Controls*, ST. GOVERNMENT NEWS, Jan. 1, 2001, at 10.

²⁵Rich, *supra* note 23, at 3968.

thirty-seven states have legislation under consideration that would institute buying clubs, bulk purchasing, and other measures to handle the soaring cost of prescription drugs.²⁶ In May of 2000, Maine passed a law, the first of its kind, to allow the state to control drug prices if the industry did not lower them significantly by 2003.²⁷ That same year, the Vermont Senate also threatened price controls if the pharmaceutical industry did not lower its prices.²⁸ Florida and Michigan recently passed legislation providing preferential treatment for state purchases to lower-priced drugs.²⁹ Massachusetts and Maine have passed laws that would allow them to purchase medicines in bulk that are sold at lower prices to prisons, hospitals, and Medicaid recipients.³⁰ The pharmaceutical industry objects to these policies as forms of price controls, and is defending itself with lawsuits to stymie these efforts.³¹ How the legal battles play out will be an important indication of the nation's evolving attitude toward the pharmaceutical industry.

C.

The Reimportation Debate

At the beginning of the discourse on policy options to alleviate the costs of drugs for the elderly, lawmakers focused primarily on whether Medicare should include a prescription drug benefit. The focus shifted, however, when stories of elderly persons traveling in caravan to Mexico and Canada in search of lower-cost drugs prompted attention from lawmakers.³² By 2001, Congressional candidates from at least eleven states had chartered buses to take people to Canada or Mexico to buy prescription drugs as a form of public protest.³³

1.

Proposed Reimportation Policies

Public attention to the increasing cost of prescription drugs culminated in several attempts in year 2000 to introduce legislation that would allow pharmaceutical reimportation.³⁴ The issue of reimportation in-

²⁶Robin Toner, *Rising Drug Costs a Powerful Issue for National and State Politicians*, N. Y. TIMES, Apr. 1, 2002.

²⁷Cowan, *supra* note 24, at 10.

²⁸*Price Controls are a Possibility in Vermont*, CHAIN DRUG REVIEW, Apr. 10, 2000, at RX 7.

²⁹Garry Boulard, *The War on Drug—Prices: States Are Taking Up the Fight to Reduce Prescription Drug Costs*, ST. LEGISLATURES, Mar. 1, 2002, at 12.

³⁰Cowan, *supra* note 24, at 10.

³¹*Id.*; Boulard, *supra* note 29, at 12. Some commentators believe that a reduction in profits would primarily affect investigational drugs with little social benefit, and that it would be highly unlikely for pharmaceutical companies to cut back on research and development with potentially “important therapeutic advantages, since they are the lifeblood of the industry.” Daniel A. Hussar, *Is There a Better Solution for the Pharmaceutical Price Problem?* DRUG TOPICS, Nov. 6, 2000, at 10.

³²Andrew Phillips & Brenda Branswell, *“The Canadian Connection”: New England Looks North to Import Cheap Prescription Drugs*, MCCLEANS, Feb. 28, 2000, at 28.

³³Cowan, *supra* note 24, at 10.

³⁴Davis, *supra* note 2, at 485.

curred a cast of illustrious characters on both sides of the debate. Noteworthy in the list of proponents of a reimportation bill was Hillary Clinton, then running for the U.S. Senate, who supported a measure to allow reimportation of approved drugs from Canada.³⁵ Representative Marion Berry (D-Ark), supported a broader measure that would allow importation and reimportation from a number of countries.³⁶ Representative Tom Coburn (R-Ok) stated, “[d]rug reimportation is a market-based solution to the problem of the rising cost of drugs.”³⁷ President Clinton also supported reimportation, saying “I think it’s wrong when drug companies sell the same drugs for a much higher price at home than they do overseas—even when those drugs are manufactured right here in America.”³⁸ It is interesting to note the bipartisan political support for reimportation—liberals see reimportation as a means to increase access to medical care, and conservatives see it as a way of dealing with the prescription drug issue without resorting to entitlement programs by instead using so-called “market-based” policies to lower costs.

Opponents of reimportation bills relied on public safety arguments to try to prevent such a measure from passing. The most vocal opposition to such bills came from members of the pharmaceutical industry. The Pharmaceuticals Research and Manufacturers of America (“PhRMA”) stated that Congress should “stop [reimportation] legislation before it can harm patients.”³⁹ The Biotechnology Industry Organization President Carl B. Feldbaum charged that these measures were political “quick fixes” that jeopardized the safety of the infirm and elderly in the name of improving access to drugs.⁴⁰ Representative John Dingell (D-Mich), the author of the PDMA, argued that a reimportation bill would leave the public vulnerable to adulterated or misbranded drugs, stating, “we must never forget that the safety and well-being of Americans comes first.”⁴¹ All Food and Drug Administration (“FDA”) Commissioners since 1969 wrote to members of Congress opposing reimportation due to the potential public health risks, a fact publicized by the pharmaceutical industry; later, however, former Commissioner David Kessler decided to support a reimportation measure.⁴² Some citizen advocacy groups also opposed reimportation. The Seniors Coalition, while approving of the spirit of these proposals, feared that the compromise of FDA’s “gold standard” in safety and efficacy would lead to increased risks to seniors.⁴³ The group instead advocated prescription drug coverage under Medicare.⁴⁴

³⁵Barbara J. Saffir, *Hillary Prescribes Importing of Drugs; Would Lower Medication Costs, She Says*, WASH. TIMES, Feb. 9, 2000, at A3.

³⁶Rep. Marion Berry, *Relieving the Burden of High-Priced Medicine*, THE HILL, Sep. 12, 2001, at 46.

³⁷Rep. Tom Coburn, M.D., *Drug Reimportation Will Drive Down Costs*, THE HILL, Sep. 20, 2000.

³⁸*Tentative Agreement Will Allow Reimport of U.S.-Made Drugs*, CHEMICAL MARKET REP., Oct. 2, 2000, at 29.

³⁹*Former FDA Chiefs Blast Import Proposal*, CHAIN DRUG REV., Sep. 25, 2000, at RX 33.

⁴⁰*BIO: Reimportation of Prescription Drugs Puts Patients at Risk*, PR NEWswire, July 18, 2000.

⁴¹Rep. John D. Dingell, *Coburn and Crowley Amendments Pose Risks*, THE HILL, Sep. 20, 2000.

⁴²*Eleven Former FDA Commissioners Warn of Dangers of Drug Reimportation To American Patients, Reports PhRMA; Every Living Former FDA Commissioner Since 1969 Says Reimportation is Dangerous*, PR NEWswire, Aug. 31, 2000; *Former FDA Chief Now in Favor of Reimporting Rx's*, DRUG TOPICS, Oct. 2, 2000, at 10. Kessler stated in his reversal: “U.S. licensed pharmacists and wholesalers—who know how drugs must be stored and handled and who would be importing them under the strict oversight of the FDA—are well positioned to satisfy import quality products rather than having American consumers do this on their own.” *Id.*

⁴³*Seniors Coalition Calls on Senate to Reject Drug Reimportation Amendments to Supplemental Agriculture Appropriations Bill*, U.S. Newswire, Aug. 2, 2000.

⁴⁴*Id.*

2.

MEDSA

The result of this debate was the MEDSA, which was passed as part of the 2001 agricultural appropriations bill.⁴⁵ MEDSA attempts to counter the high costs of prescription drugs by allowing reimportation of drugs that are shown not to pose a public health risk. It amends the Federal Food Drug and Cosmetic Act (“FDCA”)⁴⁶ to allow the Secretary of HHS to promulgate regulations allowing pharmacists and wholesalers to reimport U.S. manufactured products, and prohibits contracts restricting the reimportation of drugs by the manufacturer.⁴⁷ MEDSA addresses the public safety issue by requiring that the reimported drugs meet FDA approval standard and by setting forth detailed labeling and testing requirements for reimporters.⁴⁸ It appropriates \$23 million dollars for the FDA to implement the requirements of the Act.⁴⁹

PhRMA criticized the Act, stating that it was full of loopholes and would put American consumers at risk.⁵⁰ Democrats accused the pharmaceutical industry for gutting the bill, creating the very loopholes that undermined its effectiveness.⁵¹ According to MEDSA, drugs can initially be imported from Europe, Canada, Japan and Australia, but not from Mexico and Latin America as some Democrats had hoped.⁵² Furthermore, though contracts prohibiting parallel importation are disallowed under MEDSA, it would allow contracts that prohibited sale of reimported drugs below U.S. prices.⁵³ Though President Clinton believed that MEDSA represented “little more than a false promise to the American public,” he nonetheless signed the bill into law on October 28, 2000.⁵⁴

Perhaps the only group that wholeheartedly endorsed MEDSA was the National Community Pharmacists Association (“NCPA”).⁵⁵ Calvin Anthony, executive vice-president of the NCPA stated that MEDSA was “a high victory for the nation’s independent pharmacists,” allowing them to purchase prescription drugs at a lower cost and passing those costs on to consumers.

Under Section 804(l) MEDSA does not become effective until the Secretary of HHS issues findings that there will be no adverse health effects and approves the bill.⁵⁶ Upon the passage of MEDSA, then Secretary Donna Shalala refused to implement the bill, and in 2001 Secretary Tommy Thompson issued a letter to Congress reaffirming her decision.⁵⁷ In his letter, Secretary Thompson expressed safety concerns about allowing drug

⁴⁵H.R. Rep. No. 106-948, at 38 (2000). MEDSA was passed as section 745 of Public Law 106-387, making appropriations for Agriculture, Rural Development, Food and Drug Administration, and Related Agencies programs for the fiscal year ending September 30, 2001. *Id.*

⁴⁶21 U.S.C. §§ 301-397 (1999).

⁴⁷MEDSA, *supra* note 1, at §§ 804(a), 804(h).

⁴⁸*Id.* at §§ 804(b)-(e).

⁴⁹21 U.S.C. § 333(e).

⁵⁰*Congress Passes, President to Sign Drug Reimportation Bill, Critics Minimize Law’s Effect*, MED. MARKETING AND MEDIA, Nov. 1, 2000, at 8.

⁵¹Glenn Hess, *Democrats Accuse Pharma Industry of Gutting Drug Reimportation Bill*, CHEMICAL MARKET REP., Oct. 16, 2000, at 1.

⁵²*Congress Passes, President to Sign Drug Reimportation Bill, Critics Minimize Law’s Effect*, *supra* note 50, at 8; see MEDSA, *supra* note 1, at § 804(f).

⁵³Glenn Hess, *Democrats Accuse Pharma Industry of Gutting Drug Reimportation Bill*, CHEMICAL MARKET REP., Oct. 16, 2000, at 1.

⁵⁴James G. Dickinson, *Clinton Signs Drug Reimport Bill*, MED. MARKETING & MEDIA, Dec. 1, 2000, at 38.

⁵⁵James Frederick, *Drug Importation Bill Passes, Drawing Praise From NCPA*, DRUG STORE NEWS, Oct. 30, 2000, at 15.

⁵⁶MEDSA, *supra* note 1, at § 804(l).

⁵⁷Secretary Tommy Thompson, U.S. Dept. of Health and Human Services Response to Sen. James Jeffords on Drug Reimportation (July 9, 2001), available at <http://www.fda.gov/oc/apo/thompson/medsact.html>.

products back in the U.S. market that had not been subject to FDA oversight.⁵⁸ He doubted the cost savings that would result from the bill, noting that reimportation might not occur under the costly administrative regime envisioned by MEDSA.⁵⁹ In expressing dismay at the fact that MEDSA was never implemented, NCPA president John Carson stated: “Millions of Americans are crossing our nation’s border—both physically and via the internet—to purchase prescription drugs at lower prices with little or no assurance of safety.”⁶⁰

3.

State Reimportation Measures

Reimportation measures have also been considered by a number of New England state governments even though under the PDMA and FDCA this would be illegal.⁶¹ The Vermont Senate in 2000 considered a plan to allow Canadian pharmacists to fill prescriptions issued by Vermont doctors in exchange for opening up New England hospitals for treatment of Quebec citizens.⁶² New Hampshire and Maine have discussed similar arrangements with Quebec officials.⁶³

4.

Post-MEDSA Reimportation Amendments

In response the Bush administration’s refusal to implement MEDSA, lawmakers proposed amendments to the 2002 agricultural appropriations bill to attempt to get a reimportation measure through. HR 2330, sponsored by Representative Bernie Sanders (I-VT), would have prevented the FDA from enforcing the ban on the reimportation of FDA approved pharmaceuticals.⁶⁴ An effort at reviving the defunct MEDSA, the bill failed in the House.⁶⁵ Another bill, sponsored by Representative Gil Gutknecht (R-Minn), allowing reimportation by individual consumers for personal use, passed in the House by a wide margin.⁶⁶ A House

⁵⁸ *Id.*

⁵⁹ *Id.*

⁶⁰ Michael F. Conlan, *How Safe is the Drug Supply? Reports of Counterfeit Drugs and the Growth of E-tailing are Fanning Concerns about Drug Quality*, DRUG TOPICS, Oct. 15, 2001, at 32.

⁶¹ Phillips & Branswell, *supra* note 32, at 28.

⁶² *Price Controls are a Possibility in Vermont*, CHAIN DRUG REVIEW, Apr. 10, 2000, at RX 7; Phillips & Branswell, *supra* note 32, at 28.

⁶³ *Id.* at 28.

⁶⁴ Dana A. Elfin, *House Reimportation Amendment Fails; Personal Use Exemption Amendment Passes*, PHARMACEUTICAL L. & POL’Y, July 19, 2001, available at <http://subscript.bna.com/SAMPLES/plp.nsf/85256269004a99228525625400656cb3/fdb35968676d2ef185256a8d0073ddf9?OpenDocument>.

⁶⁵ *Id.*

⁶⁶ *Id.*

Panel later removed the amendment, ending the drug reimportation debate for at least the near future.⁶⁷ In the wake of the September 11 events, some believed that U.S. adoption of another reimportation measure was “virtually dead” due to fears of contamination by terrorists.⁶⁸ However, in April 2002, Senator Byron Dorgan (D-ND) stated that he planned to renew efforts for an importation bill from Canada.⁶⁹ Though MEDSA’s life was short-lived and it is unclear whether another reimportation measure will take its place in the future, it shows that the American political climate is warming towards the idea of reimportation as an answer to the public’s frustrations with the cost of prescription drugs. It is a seemingly convenient and cost-free solution to the problem and attracts both liberals and conservatives alike. Though safety concerns dominated the MEDSA debate and ultimately won the day, the real concern with reimported drugs, and parallel imports in general, lies in their impacts on the domestic and global drug markets.

II.

Parallel Imports and Pharmaceuticals

The primary underlying issue of a reimportation policy, though not entirely obvious and rarely addressed by politicians, is the role of intellectual property law in the pharmaceutical industry. Though this article cannot explore the many controversies surrounding this issue, the basic theme is the need to balance incentives for the pharmaceutical industry to invent new and useful products while at the same time allowing the public access to such goods. To flesh out the implications of a reimportation measure, this Part will first discuss the law and theory underlying the most important aspect of intellectual property in the pharmaceutical industry, patent protection. It will then explain why pharmaceutical prices vary so widely between geographic markets, and why this may not be such a bad thing for consumers.

A.

Patent Protection in the United States

Rather than traditional property law, which governs rights with regard to land or other goods, intellectual property law provides the norms and guidelines for the protection and distribution of ideas. In the United States, the federal protection of authorship and ideas has a basis in Art. I §8 of the U.S. Constitution, which gives Congress the power “to promote the Progress of Science and the useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.” The Founders saw the importance of a national intellectual property system, both to avoid problems of disputes

⁶⁷Kristen Hallam, *House Panel Drops Personal-Use Drug Importation*, BLOOMBERG NEWS, Nov. 8, 2001.

⁶⁸Daniel B. Moskowitz, *Washington Insight*, BUS. & HEALTH, Nov. 1, 2001, at 8.

⁶⁹Toner, *supra* note 26.

between state-granted intellectual property rights and to promote innovation throughout the nation.⁷⁰ The Patent Act of 1952 provides broad statutory guidelines for granting patents. It states: “Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.”⁷¹ According to the Act, an inventor must give evidence of three substantive requirements in order for a patent to be granted: that the invention is novel,⁷² that it is useful,⁷³ and that it is nonobvious.⁷⁴ Furthermore, the Act requires that the inventor disclose the invention in such a way that the public can make use of it.⁷⁵ Implicitly, the invention must also be of patentable subject matter.⁷⁶ Together, these substantive and procedural requirements make up the five elements of patentability. A patent is reviewed by agents in the Patent and Trademark Office, who examine the claims in the patent application for novelty, usefulness and nonobviousness. The process generally encompasses a number of rounds of revision, and takes on average two to three years.⁷⁷

Once a patent has been granted, the holder has a right to exclude others from making, using, selling, offering for sale, or importing the invention for the term of the patent.⁷⁸ These rights are not affirmative rights to be able to make, use, sell, or import the invention to the patentholder—rather, the patent holder has a legal claim against anyone who infringes these rights without permission.⁷⁹ In the United States, patents that were granted prior to 1995 have a term of 17 years from the date of issue. In accordance to the World Trade Organization Agreement on Trade Related Aspects of Intellectual Property Rights (“TRIPS”),⁸⁰ after 1995, patents granted have a life of 20 years from the date of application.⁸¹

B.

Patent Protection and Pharmaceuticals

A patent is a grant of a certain period of exclusivity during which the patent holder, usually the inventor, has control of the use, distribution, and sale of an invention. The utilitarian justification for patent rights is that giving inventors a grant of a legal monopoly, during which time they may reap the rewards of their

⁷⁰ See ROBERT P. MERGES ET AL., *INTELLECTUAL PROPERTY IN THE NEW TECHNOLOGICAL AGE* 127 - 28 (2d. ed., 2000).

⁷¹ 35 U.S.C. § 101 (2001).

⁷² *Id.* at § 102.

⁷³ *Id.* at § 101.

⁷⁴ *Id.* at § 103.

⁷⁵ *Id.* at § 112.

⁷⁶ MERGES ET AL., *supra* note 70, at 131.

⁷⁷ *Id.* at 134.

⁷⁸ *Id.* at 133.

⁷⁹ See *id.* at 134. For instance, if someone has a patent to an invention, and another party patents an invention that utilizes the first invention as a component, the second inventor must still obtain permission to use the already patented inventions to make his own invention. An affirmative right to make the invention has not been granted with the grant of the patent.

⁸⁰ See Agreement on Trade-Related Aspects of Intellectual Property Rights, April 15, 1995, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments-Results of the Uruguay Round vol. 31; 33 I.L.M. 81 (1994) [hereinafter TRIPS].

⁸¹ MERGES ET AL., *supra* note 70, at 133.

labor, provides a powerful incentive for socially beneficial innovation.⁸² These rights, of course, may be licensed to others for a price. According to utilitarian theory, the need for patents arises because inventions are “free goods,” or goods that do not decline in value with any particular use and are difficult to exclude others from using.⁸³ Without patent rights, inventors would not devote the time and resources that allow them to create innovative products that are beneficial to society as a whole.

In the pharmaceutical arena, where the costs of creating a new drug are high but the incremental costs of producing the drug once invented are small, patent protection is of central importance.⁸⁴ There are a number of reasons for the high costs of creating a new drug. In the United States and many other countries, pharmaceuticals are unique compared to other industries in terms of the protracted and intensive regulatory requirements placed upon them for government approval. Furthermore, many drugs are partially developed and then abandoned later in the research and development phase.⁸⁵ Due to these factors, drugs tend to be a riskier investment compared to other industries.⁸⁶ The exact cost of drug development is the subject of heated debate between activists, academics, and the pharmaceutical industry. Estimates range from \$56.5 million to \$802 million, depending on whether carrying costs of capital, the cost of research failures, and tax deductions are included.⁸⁷ Despite this debate, most commentators agree that the pharmaceutical industry

⁸²*Id.* at 137. Economists have challenged the view of patents as monopolies in the area of pharmaceuticals. They argue that due to the availability of competing products, the limitations placed on the length and scope of patents by regulatory systems, and brand loyalty substantially undercut the monopoly power of patents. Instead, they argue that patents should be viewed as property. See Claude E. Barfield and Mark A. Groombridge, *Parallel Trade in the Pharmaceutical Industry, Implications for Innovation, Consumer Welfare, and Health Policy*, 10 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 185, 202-02 (1999).

⁸³*Id.* at 201; W. KIP VISCUSI ET AL., ECONOMICS OF REGULATION AND ANTITRUST 820 (3d ed. 2000).

⁸⁴Barfield & Groombridge, *supra* note 82, at 208 - 10.

⁸⁵See, e.g., Andrew Pollack, *Despite Billions for Discoveries, Pipeline of Drugs Is Far From Full*, N.Y. TIMES, Apr. 19, 2002.

⁸⁶OFFICE OF TECHNOLOGY ASSESSMENT, PHARMACEUTICAL R&D: COSTS, RISKS, AND REWARDS 47 (1993) [hereinafter PHARMACEUTICAL R&D].

⁸⁷The pharmaceutical industry often cites a figure of \$500 million for the pre-tax cost of developing a new medicine, derived from a study in 1991 by the Tufts Center for the Study of Drug Development. See, e.g., PHARMA, PHARMACEUTICAL INDUSTRY PROFILE 17 (2001) (citing an analysis by the Boston Consulting Group based on a study by J.A. DiMasi et al.). The original 1991 analysis by DiMasi estimated the cost of developing a new drug to be \$231 million in 1997 dollars. The estimate includes the opportunity costs, or carrying cost of capital, for the duration of development as well as research failures. See, e.g., *id.* at 17 (2001). The figure also includes out of pocket discovery, preclinical development, and clinical trial costs. Tufts Center for the Study of Drug Development, *A Methodology for Counting Costs for Pharmaceutical R&D* 1 - 3 (2001), available at <http://www.tufts.edu/med/csdd/images/StudyMethodology.pdf>.

The \$500 million figure was challenged by a study by Public Citizen in 2001, which produced its own study based on the 1991 Tufts study and a report by the Office of Technology Assessment. PUBLIC CITIZEN, RX R&D MYTHS: THE CASE AGAINST THE DRUG INDUSTRY'S R&D "SCARE CARD" (2001), available at <http://dev.citizen.org/documents/ACFDC.PDF>, citing OFFICE OF TECHNOLOGY ASSESSMENT, PHARMACEUTICAL R&D: COSTS, RISKS, AND REWARDS (1993), available at <http://www.wws.princeton.edu/~ota/disk1/1993/9336.n.html>. Public Citizen's study attacked the numbers from the pharmaceutical industry and the Tufts Study on a number of grounds: the inclusion of opportunity costs, which Public Citizen argues should not be included since opportunity costs do not represent actual cash outlay; the use of pre-tax dollars, rather than including substantial tax deductions in the cost; and the focus on “new chemical entities” versus all drugs brought to market. PUBLIC CITIZEN, *supra*, at 3-4. The Public Citizen study also pointed to high pharmaceutical profits as an indication of the fact that drug development is not, in fact, a risky business. *Id.* at 11. Revising the estimates based in its own methodology, Public Citizen arrived at a figure of \$56.6 million. *Id.* at 6.

Soon thereafter, the Tufts Center issued an update to its 1991 study, using similar methodology, with a new estimate of \$802 million dollars for drug development. Tufts Center for the Study of Drug Development, *News Release: Tufts Center for the Study of Drug Development Puts Cost of a New Prescription Medicine at \$802 Million* 1 (2001), available at <http://www.tufts.edu/med/csdd/images/NewsRelease113001pm.pdf>. The estimate is in 2000 dollars, and includes the cost of failures and opportunity costs of the potential return of the capital spent on research and development. *Id.* at 2. Compared to the Center's 1991 estimate of \$231 million, the new figure was a 250% real increase in drug development costs. *Id.* (estimate in 1987 dollars). The study's principal investigator, Dr. Joseph A. DiMasi, attributed this to an increase in the costs of clinical trials, particularly for the study of drugs affecting chronic and degenerative diseases. *Id.* at 2. According to the study, the

is a particularly capital- and research-intensive one.⁸⁸

The combination of the high cost of drug development and the low cost of copying drugs creates a market failure in which, without government intervention, few would make the investment to produce such goods and a socially suboptimal level of invention would result.⁸⁹ Patents provide one solution to this market failure by creating a legal right in the inventive information that allows the owner to exclude others, and thus charge prices above competitive prices (obtaining so-called monopoly rents).

The optimal length of a patent is theoretically the amount of time required to obtain a return that will provide enough incentive for an inventor to create a beneficial invention.⁹⁰ As the expected patent life of a drug is limited by the time it takes for the FDA to approve the drug as safe and effective,⁹¹ pharmaceutical companies typically enjoy less exclusivity than other industries. Because of the long delay between patent application and FDA marketing approval, Congress passed the Drug Price Competition and Patent Term Extension Act of 1984,⁹² which allows new drugs to receive patent term extensions of up to five years. Once a drug's patent expires, it may then be manufactured and sold by generic drug companies. The resulting competition by generic companies leads the prices generally to drop significantly.

Though a patent system was important enough to warrant constitutional protection, the need to provide incentives for innovation must also be balanced with the need for the dissemination of beneficial goods and information to the public. The patent system tries to strike this balance in two ways. First, when a patent is registered, the information held within it describing the invention is made freely available to the public (although the practice of the invention is, of course, protected). Second, the term of the patent allows the patent holder to extract monopoly rents for a limited period of time, after which others may make or use the product with impunity. Though patent protection is theoretically meant to help society overall, granting patents that are too long in duration or too broad in scope may counteract the beneficial aspects of patent protection.

There are a number of criticisms against the strong intellectual property protection in the United States that ultimately allows the pharmaceutical industry to charge such high prices for prescription drugs. The public finds it difficult to understand why the United States has been reluctant to intervene on high drug prices when it funds a large amount of basic science research that eventually leads to pharmaceutical products.⁹³ Further, a number of commentators believe that patent protection has been the primary barrier to the distribution of desperately needed drugs, especially in the case of AIDS drugs in sub-Saharan Africa.⁹⁴ These critics, though rarely advocating an absolute denial of intellectual property protection, would limit it through compulsory licensing⁹⁵ or shorter patent terms.

growth rate for capitalized clinical costs was more than five times greater than the growth rate for pre-clinical research and development costs. *Id.*

⁸⁸ See, e.g., Alan M. Fisch, *Compulsory Licensing of Pharmaceutical Patents: An Unreasonable Solution to an Unfortunate Problem*, 34 JURIMETRICS J. 295, 302-304 (1994); Barfield & Groombridge, *supra* note 82, at 208 - 10.

⁸⁹ Barfield & Groombridge, *supra* note 82, at 201.

⁹⁰ For an economic discussion of optimal patent life, see VISCUSI ET AL., *supra* note 83, at 806 - 10.

⁹¹ PHARMACEUTICAL R&D, *supra* note 86, at 82.

⁹² Pub. L. 98- 417, 98 Stat. 1585 (codified at 35 U.S.C. § 156 (2000)).

⁹³ See, e.g., PUBLIC CITIZEN, *supra* note 87, at 7 - 10.

⁹⁴ See, e.g., Rosalyn S. Park, *International Drug Industry: What the Future Holds for South Africa's HIV/AIDS Patients*, 11 MINN. J. GLOBAL TRADE 125 (2002).

⁹⁵ See, e.g., Mary K. Schug, *Promoting Access to HIV/AIDS Pharmaceuticals in Sub-Saharan Africa Within the Framework of International Intellectual Property Law*, 19 LAW & INEQ. 229 (2001).

C.

Definition of Parallel Imports

Parallel imports, also referred to as “gray market” goods, are products that are produced by an authorized manufacturer in one country and then exported to another country without permission of the manufacturer.⁹⁶ This occurs in cases where the authorized dealer is selling the product at different prices in different countries. When a product is sold at a lower price in a certain region, there is a market for those lower-priced goods in a region where the good is normally priced higher. As an illustration, take a bottle of Chanel No. 5. Say that all Chanel No. 5 is manufactured in the United States, but a one-ounce bottle sells in the Mexican market for \$40 and in the Canadian market for \$60. There is an incentive to buy those bottles of Chanel No. 5 in the Mexican market for \$40 take them to Canada for profit, thus resulting in another distribution channel to the Canadian market. The term “parallel imports” refers to this second line of goods that is being imported “parallel” to the authorized distribution from the United States to Canada.⁹⁷ The term “reimportation” refers to the narrower situation where the goods are imported to the original country of manufacture, in this case the United States.⁹⁸

Parallel imports are distinct from black market goods, which are the unauthorized production of trademarked, copyrighted, or patented goods. The manufacture of parallel imports is fully authorized. Instead, the question with parallel imports is whether the original rightsholder has right to control the importation or exportation of the goods after sale in a particular market.

D.

Significance of Parallel Imports in the Pharmaceutical Industry

The issue of parallel imports is of increasing importance in the area of pharmaceuticals in large part due to the drastic price differentials between prescription drugs sold in different countries. For instance, a thirty 20mg pill supply of Prosilic, an anti-ulcer drug manufactured by Merck, cost \$120.45 in the United States in 1999, but in Canada and Mexico sold for \$51.60 and \$34.50, respectively.⁹⁹ The differences between prices in nations that do not offer patent protection for drug products is even more stark; for example, a 20 mg tablet of Omeprazole sold for \$2.91 in the U.S. and for \$.06 in India.¹⁰⁰

⁹⁶See WARWICK A. ROTHNIE, PARALLEL IMPORTS 1, 68 n.208 (1993).

⁹⁷*Id.* at 1.

⁹⁸The debate on parallel importation of pharmaceuticals is primarily concerned with the reimportation of drugs manufactured in the United States. Importation of drugs manufactured in other countries is limited under 21 U.S.C. § 381(a) - (c) (2002).

⁹⁹Prescription Drugs with Foreign Labels, Prepared for Sen. Henry Waxman, Minority Staff, Special Investigations Division, Committee on Government Reform, U.S. House of Representatives, October 11, 2000, at 1. In Canada and Mexico, the drug sells under the name “Losec.” *Id.*

¹⁰⁰KEITH E. MASKUS, PARALLEL IMPORTS IN PHARMACEUTICALS: IMPLICATIONS FOR COMPETITION AND PRICES IN DEVELOPING COUNTRIES 53 tbl.2 (2001) (Final Report for the World Intellectual Property Organization). The numbers refer to wholesale prices. U.S. price refers to pills sold in 1996; India price refers to pills sold in 1997.

A number of factors contribute to the differential pricing of drugs in different markets, many of which are outside the control of pharmaceutical manufacturers. Most importantly, the United States is one of the few countries that do not regulate the prices of drugs.¹⁰¹ In Europe, for example, each country negotiates prices with pharmaceutical companies to obtain the best price they can for their nationals.¹⁰² The United States, on the other hand, has traditionally allowed the free market to dictate the costs of prescription drugs. Other external factors that lead to geographically disparate pharmaceutical prices are the variance of patent protection in different countries and inflation and exchange rate differentials.¹⁰³

The pricing practices that pharmaceutical manufacturers can control are also based on market factors such as variation in income and tastes. In countries with more elastic demand for drugs, for example, the profit-maximizing price is lower.¹⁰⁴ In addition, many drug companies have recently, in the wake of public outcry over the lack of affordable drugs in developing countries, created programs to offer lower-priced or free drugs to certain needy countries.¹⁰⁵ For instance, Pfizer recently offered Difulcan, a meningitis medication, at no cost to South Africa for two years.¹⁰⁶ Though one may question the motives of such programs, the result is huge pricing differentials in the international market.¹⁰⁷ Such programs may make it harder to justify the high prices of drugs in the United States, and create further pressure on American health officials and legislators to take action to reduce prescription drug prices.¹⁰⁸

Proponents of parallel imports discount these reasons, citing corporate greed and extraction of the highest possible profits as the primary motivating factors. The following section will explain how differential pricing may not reduce consumer welfare and, in fact, is beneficial to society by reducing societal losses resulting from monopoly pricing.

E.

Economic Analysis of Pharmaceutical Price Discrimination

The disparate pricing of pharmaceuticals between the United States and other countries that has engendered much of the public outrage against U.S. prices is a form of price discrimination. Price discrimination is the application of different prices to different markets for the same good—for instance, selling a theater ticket at a lower price during a weeknight versus the weekend or offering lower prices for senior citizens. Generally, price discrimination refers to cases where producers charge higher prices to those who are willing to pay more for the product. Geographic price discrimination of pharmaceuticals, the issue underlying reimportation, has resulted in the wide disparity of prices described above.

¹⁰¹Davis, *supra* note 2, at 507.

¹⁰²See Hugh Brett, *Parallel Imports in Europe*, Derwent Information (2000), at <http://www.derwent.com/ipmatters/features/parallel.html>.

¹⁰³INTERNATIONAL FEDERATION OF PHARMACEUTICAL MANUFACTURERS ASSOCIATIONS, *PARALLEL TRADE: RECIPE FOR REDUCING PATIENTS' ACCESS TO INNOVATIVE AND HIGH QUALITY MEDICINES 1* (2000), *available at* <http://www.ifpma.org/pdfifpma/ParallelTrade.pdf>; Barfield & Groombridge, *supra* note 82, at 245 - 46.

¹⁰⁴Davis, *supra* note 2, at 507.

¹⁰⁵See Robert Lenzner, *The Effects Could be Devastating*, FORBES, Nov. 27, 2000, at 156.

¹⁰⁶*Id.*

¹⁰⁷An ancillary issue is the heightened incentive for illegal arbitrage if prescription drugs are available at such lower prices in developing countries in comparison to developed countries. See Bruce Stokes, *No Easy Cure*, 968 NAT'L J. 968 (2001).

¹⁰⁸See *id.*

Price discrimination is frowned upon in antitrust law as it typically shifts economic surplus from consumers to producers. However, where intellectual property rights are involved, price discrimination, though certainly benefiting producers, may not necessarily have an adverse effect on consumers.¹⁰⁹ This is in part because patented drugs already have monopoly rights for the duration of the patent. Under this monopoly, the patent holder may price the based product to maximize profit, or where marginal revenue equals marginal cost.¹¹⁰ The result is a price above the market equilibrium, creating a loss to consumers having to pay more for the good, and a deadweight loss to society by preventing people who could afford the good at the market price, but cannot afford the monopoly price, from buying the good.¹¹¹ Our current patent system accepts this tradeoff between societal losses incurred from monopoly and the incentives necessary for producers to innovate. The following figure is a typical depiction of the producer surplus (profit), consumer surplus,¹¹² and deadweight loss that results from monopoly pricing:

Figure 1: Monopoly

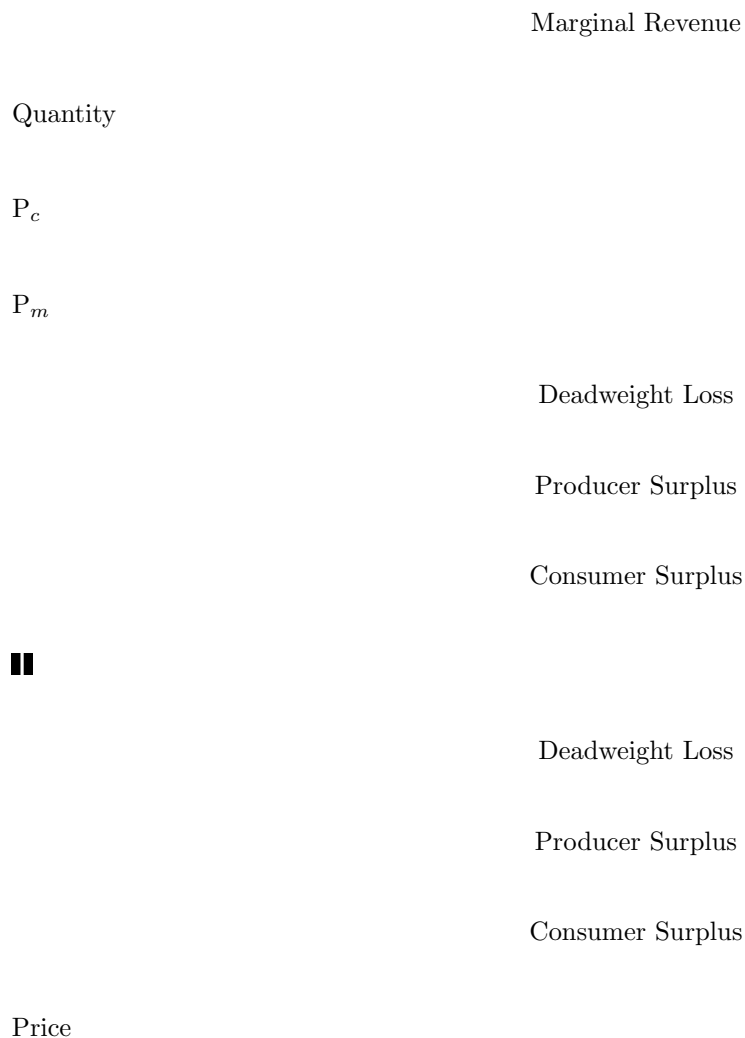


¹⁰⁹William Fisher, *Property and Contract on the Internet*, 73 CHI.-KENT L. REV., 1203, 1238 - 39 (1998).

¹¹⁰For a discussion of the derivation of this model, see VISCUSI ET AL., *supra* note 83, 78 - 80.

¹¹¹Losses to consumers due to paying higher prices are not losses to society because the producers gain.

¹¹²Consumer surplus is the difference between what a consumer is willing to pay for a good (their “personal price”) and the price that it costs them.



Price discrimination lowers the deadweight loss associated with monopoly power by allowing some consumers to buy the goods at a cost that they can afford. The figure below provides a depiction of the theoretical effects of price discrimination on consumer surplus, producer surplus, and deadweight losses.¹¹³

Figure 2: Price Discrimination Under Monopoly

¹¹³This figure is adapted from Fisher, *supra* note 109, at 1238; *but see* Donnelly, *supra* note 127, at 502 (noting that total welfare increases only if greater quantity of the goods are sold).

Demand

Marginal Revenue

Quantity

Price

P_c

P_{m1}

■

P_{m2}

P_{m3}

P_{m4}

Marginal Cost

Demand

Marginal Revenue

Quantity

Price

P_c

P_{m1}

P_{m2}

P_{m3}

P_{m4}

Deadweight Loss

Producer Surplus

Consumer Surplus

■

Deadweight Loss

Producer Surplus

Consumer Surplus

The effect of price discrimination on consumer surplus, compared to the monopoly price scenario, is unknown—either an increase or a decrease could occur. Deadweight loss decreases, while producer surplus increases. Economic theory would hold that such result is ultimately helpful to society. The increase in producer surplus is not considered a loss, but is a benefit to society overall as it presents a positive incentive for innovation.¹¹⁴

This analysis also applies to the discriminatory pricing of pharmaceuticals in different countries. Since the abilities to pay for drugs, in real terms, are very different on average from country to country, the difference in pricing roughly matches consumer willingness to pay. At the same time, much of the objection to high pharmaceutical prices comes from the United States, which has the highest drug prices of any country and the highest average willingness to pay for consumers. The reimportation issue arises because those U.S. consumers with lower willingness to pay are priced out of the U.S. market, whereas they would be able to afford drugs sold at foreign prices. The geographic groupings for consumer willingness to pay is therefore only approximate, and deadweight loss occurs in each market as consumers at the low end are priced out. A graphical depiction of this may look as follows:

Quantity

Figure 3: Price Discrimination in Geographical Markets

¹¹⁴Fisher, *supra* note 109, at 1238.

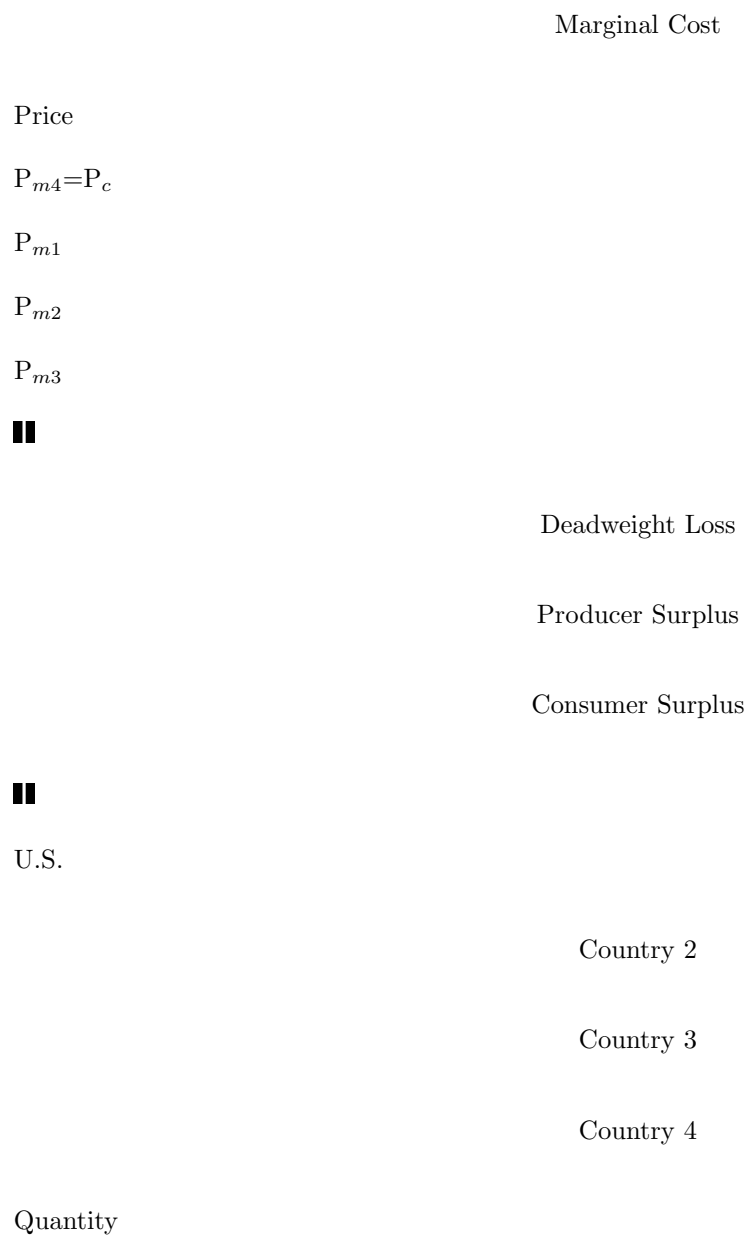


Figure 3: Price Discrimination in Geographical Markets

Marginal Cost

Price

$P_{m4}=P_c$

P_{m1}

P_{m2}

P_{m3}

Deadweight Loss

Producer Surplus

Consumer Surplus

U.S.

Country 2

Country 3

Country 4

As the figure shows, each geographic market has a separate demand curve based upon its inhabitants' willingness to pay. The United States, the world's largest market in drugs, has the highest average willingness to pay for a drug as well as the highest prices. Country 2 represents a country with price controls that has negotiated well for its drug prices such that consumer surplus exceeds deadweight loss by a large amount. Country 3 represents a country that has negotiated poorly for its prices, leading to a large amount of deadweight loss with respect to consumer surplus. Country 4 represents a developing country that has been the recipient of drugs at the manufacturer's marginal cost through a donation or philanthropic program.

Differential pricing reduces deadweight losses, leading ultimately to societal gains, either to consumers in lower price markets who pay less, or to producers who gain from increased profits, which ultimately provide further incentives to innovate beneficial products for society. Though differential pricing according to geographic markets does not correspond exactly to global willingness to pay, which would optimize results, geographic markets are a good approximate, reducing deadweight losses that would occur if no price discrimination were allowed.¹¹⁵ It is difficult for the American consumer to fathom how it can help them that pharmaceutical manufacturers are pricing medicines in foreign countries at half the cost they have to pay in the United States, especially if they cannot afford U.S. prices. Therefore, the proponents of reimportation generally have little trouble convincing consumers and politicians that such pricing is inherently unfair and harmful.

III.

Legal Treatment of Parallel Imports

U.S. law and international treaties on the parallel imports, though not a focus of the reimportation debate, have the potential play an important role. A key principle is the exhaustion of intellectual property rights, which dictates the conditions under which a sale of a protected good results in loss of certain intellectual property rights in that particular good to the original manufacturer. In the United States, the Supreme Court has followed the principle of international exhaustion for copyrighted goods, allowing parallel importation under the first sale doctrine. On the other hand, a recent Federal Circuit case applied the national exhaustion principle to patented goods, limiting the first sale doctrine to those goods sold first in the United States. The decision thus limits parallel imports and poses potential questions about the legality of reimportation policies. The European Union ("EU"), on the other hand, applies the doctrine of regional exhaustion to parallel imports, allowing parallel imports throughout the EU for European products. International agreements, such as TRIPS, adopt a primarily deferential approach, allowing each country to apply its own policies on parallel imports. The following sections will attempt to provide an understanding of the divergent approaches to parallel imports and the policies behind them.

¹¹⁵For a discussion of the effects eliminating global price discrimination, see Section IV.A.

A.

United States

Though patent protection is the most significant source of protection for pharmaceutical products, a discussion of U.S. copyright and trademark laws on parallel importation is helpful for understanding the different rationales behind each the differing approaches. This section will delineate the U.S. approach to parallel imports in copyrighted, trademarked, and patented goods.

1.

Copyrighted Goods

The latest word on the legality of parallel imports of copyrighted goods is *Quality King Distributor, Inc. v. L'Anza Research International, Inc.*¹¹⁶ In *L'Anza*, the Supreme Court found that the reimportation of hair products with copyrighted labels into the U.S. at a lower cost did not infringe upon the rights of the copyright holder. Avoiding the policy implications of such a decision, the court relied upon a textual interpretation of the applicable provisions of the Copyright Act. Section 109(a), which codifies the first sale doctrine, states:

Notwithstanding the provisions of section 106(3), the owner of a particular copy . . . lawfully made under this title, or any person authorized by such owner, is entitled, without the authority of the copyright owner, to sell or otherwise dispose of the possession of that copy. . . .¹¹⁷

The Court read this provision in conjunction with § 602(a), governing imports in copyrighted goods, which states that:

Importation into the United States, without the authority of the owner of copyright under this title, of copies or phonorecords of a work that have been acquired outside the United States is an infringement of the exclusive right to distribute copies . . . under section 106. . . .¹¹⁸

The Court reasoned that because the prohibition on importation is directly linked to the exclusive right to distribution granted under §106(3), which is limited by §109(a), the first sale doctrine applies to imported goods as well as domestic goods.¹¹⁹ U.S. copyright law thus follows the principle of international exhaustion, meaning that a first sale abroad can exhaust the right of the copyright holder to control the sale of the good. Under this construction of the first sale doctrine, copyright law does not limit the reimportation of copyrighted goods.¹²⁰

¹¹⁶*Quality King Distributor, Inc. v. L'Anza Research International, Inc.*, 523 U.S. 135 (1998).

¹¹⁹*L'Anza*, 523 U.S. 144.

¹²⁰Although Justice Ginsberg's concurrence emphasizes that the holding does not extend to good manufactured abroad rather than in the United States. *Id.* at 154.

2.

Trademarked Goods

The limitation on importation of trademarked goods comes from the Trademark Act and the Tariff Act.¹²¹ The Trademark Act Section 42 prohibits the import of products with marks that “copy or simulate” a registered U.S. trademark.¹²² Section 526 of the Tariff Act further prohibits the importation of goods of foreign manufacture if such the goods bear the trademark of a U.S. entity, unless the owner has given written permission.¹²³ Prior to 1999, the Customs Service regulations under the Tariff Act to allowed for exceptions to the ban on parallel imports where: 1) the same entity owns the U.S. and foreign trademark; 2) the foreign and domestic trademark owners are parent and subsidiary companies or are otherwise subject to common ownership or control; or 3) goods manufactured abroad bear a recorded trademark or trade name applied under authorization of the U.S. owner. In *K-Mart Corporation v. Cartier*, the U.S. Supreme Court struck down the third exception, stating that regardless of whether the use of the trademark is authorized, goods manufactured abroad are not exempt from the statute.¹²⁴ A U.S. trademark owner therefore has the ability to reject goods made abroad under the same authorized trademark. Later, in *Lever Brothers Company v. United States*, the D.C. Circuit held that the second exception granting affiliates the right to import foreign-manufactured goods under a U.S. registered trademark does not apply to goods that are physically different from the goods manufactured in the United States.¹²⁵ In response to *Lever*, the Customs Service in 1999 revised its regulations to include a section on “Restricted Gray Market Goods,” and included a provision that prohibits importation of goods manufactured by affiliates that are “physically or materially” different from the authorized product.¹²⁶ Therefore, trademark law would prohibit the reimportation of goods only if they were materially different from the goods sold originally in the U.S.

3.

Patented Goods

Though historically U.S. law has not been entirely clear on the issue of exhaustion for patented goods, a recent Federal Circuit case strongly asserted the principal of national exhaustion. As stated before, the Patent Act grants patent holders the exclusive right to import the patented goods, and therefore it would seem that the patent holder has the right to block reimportation of the good. However, this right is constrained by

¹²¹Trademark Act of 1946, 15 U.S.C. §§ 1051 – 1127 (2000) [hereinafter Trademark Act]; Tariff Act of 1930, 19 U.S.C. 1304 – 168 [hereinafter Tariff Act]. See also Tait R. Swanson, *Combating Gray Market Goods in a Global Market: Comparative Analysis of Intellectual Property Laws and Recommended Strategies*, 22 HOUS. J. INT’L L. 327, 332 (2000); Nancy T. Gallini & Aidan Hollis, *A Contractual Approach to the Gray Market*, 19 INT’L REV. L. & ECON. 1, 7 - 8 (1999).

¹²²Trademark Act § 42; ROTHNIE, *supra* note 96, at 69.

¹²³Tariff Act § 526.

¹²⁴*K Mart Corporation v. Cartier*, 486 U.S. 281, 293 - 94 (1988).

¹²⁵*Lever Brothers Company v. United States*, 981 F.2d 1330, 1338 - 39 (1994).

¹²⁶19 C.F.R. 133.23(3).

the same exhaustion of rights principles as described with the first sale doctrine of copyright law.¹²⁷ An important question is exactly how far the first sale doctrine extends, as it is not codified in the Patent Act. If the exhaustion occurs nationally, only sale within the U.S. will lead to the exhaustion of the patent right. If exhaustion occurs internationally, U.S. patent holders may not have the right to block parallel imports. In *Boesch v. Graff*, decided in 1890, the Supreme Court first announced the national exhaustion doctrine, declaring illegal the importation of goods that were manufactured and first sold abroad.¹²⁸ However, in *Curtiss Aeroplane v. United Aircraft*, the Second Circuit followed the international doctrine of exhaustion, allowing the importation of planes manufactured abroad under an exclusive license grant by the patent holder.¹²⁹

The Federal Circuit recently reiterated the national exhaustion principle in *Jazz Photo v. International Trade Commission*.¹³⁰ In *Jazz Photo*, the defendant purchased used single-use cameras casing in the United States, refurbished them abroad, and attempted to sell them back in the United States.¹³¹ In deciding on the issue of whether importation of these refurbished cameras constituted infringement, one of the central issues was the exhaustion of rights:

Underlying the repair/reconstruction dichotomy is the principle of exhaustion of the patent right. The unrestricted sale of a patented article, by or with the authority of the patentee, exhausts the patentee's right to control further sale and use of that article by enforcing the patent under which it was first sold. . . . United States patent rights are not exhausted by products of foreign provenance. To invoke the protection of the first sale doctrine, the authorized first sale must have occurred under the United States patent.¹³²

The court found that those cameras that had been sold by the authorized manufacturer in the United States did not infringe upon the U.S. patent; however, those that were first sold abroad did infringe.¹³³

The decision of the Federal Circuit seems to resolve the issue of national versus international exhaustion with regard to patented goods and provides legal ammunition to those who oppose pharmaceutical reimportation. On the other hand, the decisions of *Curtiss Aeroplane* and the *L'Anza* decision cut in the direction of international exhaustion. If legal challenges to parallel imports of patented goods take place under *Jazz Photo*, the Supreme Court may be required to settle the issue once and for all.

¹²⁷See Darren E. Donnelly, *Parallel Trade and International Harmonization of the Exhaustion of Rights Doctrine*, 13 SANTA CLARA COMPUTER & HIGH TECH. L.J. 445, 450 n.21 (1997); see, e.g., *Jazz Photo Corp. v. International Trade Comm'n*, 264 F.3d 1094, 1105 (Fed. Cir. 2001).

¹²⁸*Boesch v. Graff*, 133 U.S. 697, 702 - 03 (1890).

¹²⁹*Curtiss Aeroplane & Motor Corp. v. United Aircraft Eng'g Corp.*, 266 F. 71 (2d Cir. 1920) (following *Holiday v. Mattheson*, 24 Fed. 185 (S.D.N.Y. 1885), which found valid the reimportation of goods manufactured in the United States and sold abroad to without permission of the U.S. patent holder).

¹³⁰*Jazz Photo v. Int. Trade Comm'n*, 264 F.3d 1094, 1105 (Fed. Cir. 2001) (citing *Boesch*, 133 U.S. at 701 - 03).

¹³¹*Id.* at 1098 - 1101.

¹³³*Id.* at 1111.

4.

Interests Underlying Differing Judicial Approaches

Though court decisions seem to vary widely on the issue of exhaustion, they indicate the different underlying principles behind intellectual property protection. In the case of the parallel importation of patented goods, the Supreme Court has explained the first sale doctrine in labor-desert terms, saying, “The test has been whether or not there has been such a disposition of the article that it may fairly be said that the patentee has received his reward for the use of the article.”¹³⁴ In other words, the profits received upon first sale of the patented good is all the inventor really deserves—any more would be unduly enriching the inventor and wrongfully extending the grant of monopoly to the detriment of the public. Though not stated in *L’Anza*, the free flow of information for the benefit of the public is also a strong concern in copyright law. On the other hand, in the trademark area courts and legislators are most concerned with the consumer protection, and little to no attention is paid toward the issue of the free flow of goods. This is in part because much of trademark law itself is consumer-oriented, rather than concerned with incentives and rewards, as copyright and patent law are.

The competing interests of consumer protection, the free flow of goods and incentive for invention come to a head with the parallel importation of pharmaceuticals. Many of the drugs at issue are both patented and utilize trademarks that make them recognizable to the public. The understanding of the heightened risks to consumers through pharmaceutical products was the impetus of Congress’s passage of the PDMA. Congress recognized the need for greater consumer protection in the area of drugs. However, neither Congress nor the courts have addressed the utilitarian theory underlying patent law as a rationale for the prohibition on pharmaceutical parallel imports, making measures to remove the prohibition rest solely on overcoming the consumer protection justification. By doing so, the primary hurdle for implementing a reimportation plan has become the safety issue.¹³⁵

B.

The European Approach of Regional Exhaustion

The EU takes a different position on the parallel importation of protected goods, following the rule of “regional” or “community” exhaustion.¹³⁶ This means that a first sale within any country in the EU will exhaust the rights of the original rights holder, regardless of the fact that each country individually confers its own set of rights when it grants them.¹³⁷ The exhaustion is limited, however, by the rights holder’s consent to the first sale. If the article is sold without express or implicit authorization of the rights holder, the rights are not exhausted.¹³⁸ This bar appears to be relatively low—though sale under a compulsory

¹³⁴*United States v. Masonite Corp.*, 316 U.S. 265, 278 (1942).

¹³⁵See Davis, *supra* note 2, at 510.

¹³⁶Marleen Van Kerckhove & David Perkins, *European Community and International Exhaustion: Shades of Grey*, 671 PLI/PAT 93, 99 (2001).

¹³⁷*Id.* at 99.

¹³⁸ROTHNIE, *supra* note 96, at 125; Donnelly, *supra* note 127, at 476 - 77.

license scheme would not exhaust a patent,¹³⁹ the “simple fact of a lawful release on the foreign market” would indicate consent.¹⁴⁰

The legality of parallel importation of patented goods between member nations has important effects on the pharmaceutical trade in the EU. As prescription drug prices are fixed by the government in the various countries in Europe, the opportunity for buying drugs cheaply in one country, such as Greece, and reselling them to another country, such as England, is quite attractive.¹⁴¹ The ability for such arbitrage of retail drug prices within the EU is only limited by the requirement that the drugs be repackaged so that it can be re-sold in another country.¹⁴² The availability of parallel imports in Europe has arguably had a large impact on the pharmaceutical market: in the UK, over 10% of drugs sold are parallel imports, and Europe’s share of the global pharmaceutical market has decreased from 32% in 1992 to 22% in 2002.¹⁴³ The effects are expected to increase as more eastern bloc countries, with even lower pharmaceutical prices, join the EU. Though the EU has at this time prioritized the notions of free trade above the objections of the pharmaceutical industry, the effect on consumers is yet to be definitively studied.

C.

International Agreements and Parallel Imports

Intellectual property pose challenges to the international trade regime: more industrialized countries want greater intellectual property protection because they are more technologically enfranchised, whereas lesser developed countries, where manufacturing is cheaper, prefer less stringent intellectual property protection.¹⁴⁴ The recent trend in international agreements is offering increased intellectual property protection as a whole. However, these agreements have done little in the way of addressing the issue of parallel imports. Therefore, the nations can adopt whatever policies they see fit with regards to allowing parallel imports or not, so long as they treat other nations in the same fashion.

¹³⁹*Id.* at 474.

¹⁴⁰ROTHNIE, *supra* note 96, at 125.

¹⁴¹Brett, *supra* note 102.

¹⁴²*Id.*

¹⁴³Ben Hirschler, *Firms Step Up Attack on Low European Drug Prices*, REUTERS ENGLISH NEWS SERVICE, Jan. 9, 2002, available at <http://lists.essential.org/pipermail/ip-health/2002-January/002566.html>.

¹⁴⁴Michael A. Ugolini, *Gray Market Goods Under the Agreement on Trade-Related Aspects of Intellectual Property Rights*, 12 TRANSNAT’L LAW. 451, 452 - 53 (1999).

1.

TRIPS

TRIPS incorporates basic approaches to international trade, including the rule of “national treatment,” which requires that members treat other members no less favorably than it would its own citizens.¹⁴⁵ In addition, similar to the GATT and WTO agreements, TRIPS establishes “most favored nation” status for member nations, meaning that if a member is granted the right to treat its nationals differently from those of other members, it may not differentiate in its treatment of other nations, whether favorably or unfavorably.¹⁴⁶

The major provisions of TRIPS include: mandating intellectual property protection, establishing patent rights for process and product patents, and establishing the conditions for compulsory licensing.¹⁴⁷ Though providing rather stringent intellectual property protection compared to previous bilateral and multilateral treaties, in terms of parallel imports, TRIPS is highly deferential to the laws of the individual country. The issue of exhaustion and territoriality is addressed directly in Article 6, which states: “For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.” Though TRIPS requires border enforcement in countries to prevent the flow of black-market goods, no such requirement exists for parallel imports.¹⁴⁸

2.

NAFTA

The North American Free Trade Agreement (“NAFTA”)¹⁴⁹ contains a number of provisions heightening the protection of intellectual property for rights holders in Mexico, Canada and the United States.¹⁵⁰ NAFTA does not address parallel imports or exhaustion of rights directly.¹⁵¹ Therefore, the issue parallel imports remains up to the individual nation.¹⁵² Similar to TRIPS, NAFTA requires border enforcement of pirated goods, but enforcement of parallel imports is the choice of the individual nation.¹⁵³

¹⁴⁵TRIPS, *supra* note 80, at art. 3; Ugolini, *supra* note 144, at 454.

¹⁴⁶*Id.* at 455; TRIPS, *supra* note 80, at art. 4.

¹⁴⁷*Id.* at arts. 27, 31; Ugolini, *supra* note 144, 459 - 60.

¹⁴⁸TRIPS, *supra* note 80, at art. 51 n. 13; Ugolini, *supra* note 144, 461.

¹⁴⁹North American Free Trade Agreement, Dec. 17, 1992, Can.-Mex.-U.S., 32 I.L.M. 289 (containing chs. 1-9), 32 I.L.M. 605 (containing chs. 10- 22) (1993) [hereinafter NAFTA].

¹⁵⁰Lars Noah, *NAFTA's Impact on the Trade in Pharmaceuticals*, 33 Hous. L. Rev. 1293, 1298 - 99 (1997); *see generally* NAFTA, *supra* note 149, ch. 17.

¹⁵¹Noah, *supra* note 150, at 1303.

¹⁵²Charles S. Levy & Stuart M. Weiser, *The NAFTA: A Watershed for Protection of Intellectual Property*, 27 INT'L LAW. 671 (1993).

¹⁵³*Id.* at 671.

D.

Summary

The legal approach to parallel imports differs from nation to nation. The U.S. treats different types of goods differently, allowing parallel imports for copyrighted goods, applying more restrictions in trademarked goods. The recent decision of *Jazz Photo* reasserts the national exhaustion principle, disallowing parallel imports of goods first sold abroad. Thus, a United States policy to allow reimportation of pharmaceuticals may be subject to legal challenge. The EU, on the other hand, allows parallel imports between member nations. These various approaches are not clarified or harmonized by international treaties.

IV.

Implications of Pharmaceutical Reimportation

Though the proponents of reimportation may have noble motives, notably, that of providing affordable drugs to the elderly infirm who cannot afford them, there are many compelling reasons why reimportation is not the best solution to the high cost of prescription drugs. Though empirical evidence is scarce, following sections will attempt to delineate the potential national and international implications of a U.S. reimportation policy.

A.

Prices and Supply

If a reimportation plan such as MEDSA is effectuated in the United States, the effects on prices is unclear. In theory, unfettered reimportation,¹⁵⁴ and parallel imports in general, will reduce the incentive for companies to charge different prices in different markets because of the ability for intermediaries to buy in lower-price markets and sell in higher-price markets. In a world without price discrimination, the company would only issue drugs at one price. As described in Section II.E, the effect of price discrimination is a certain increase in producer surplus and a certain decrease in deadweight loss, which are overall societally beneficial effects. Whether consumer surplus increases or decreases depends on exactly what prices are charged to which consumers. In general, the likely effect is that those consumers that live in markets where drug prices originally were very high, such as the United States, will now be able to purchase drugs for less, increasing consumer surplus in the more advantaged countries. However, those countries formerly with very low drug

¹⁵⁴Note that MEDSA would not have resulted in unfettered reimportation as the countries of import were limited.

prices will experience an increase in drug costs. Allowing parallel importation may ultimately result no drugs being sold in developing countries that would otherwise be charged lower prices for the drugs, resulting in deadweight loss for those entire markets.¹⁵⁵ Revising Figure 3, which depicted price discrimination in various markets, to reflect a single global price would yield the following possible results:

Price

Quantity

Figure 4: Global Single Price Model



Price

Quantity

¹⁵⁵Donnelly, *supra* note 127, at 502 - 03.

Figure 4: Global Single Price Model



The results of global pharmaceutical pricing are increased consumer surplus in richer nations, decreased consumer surplus in very poor nations, and a decrease in producer surplus overall.

Though in theory, one might expect drug prices to be reduced significantly in the United States if a reimportation plan were put in place given the differential prices between nations, a number of factors could undermine this result. First, the cost saving derived from parallel trade could potentially be primarily absorbed by the distributors and middlemen engaged in parallel trading, and secondarily to hospitals and pharmacists.¹⁵⁶ Some commentators believe that consumers would receive little to none of the benefit from

¹⁵⁶Barfield & Groombridge, *supra* note 82, at 250. Recall that the pharmacy industry was a strong supporter of MEDSA.

parallel trade.¹⁵⁷ Second, as noted by Secretary Thompson, under a regime such as MEDSA with costly safety and labeling requirements, there may only be participation for the most demanded drugs, and the cost savings may be reduced for the public. Lastly, reimportation itself imposes outside costs, such as shipping and packaging, which would curb cost savings.

Though the effect of a reimportation policy to lower prices to U.S. consumers is tenuous, a successful effort to reducing geographic price discrimination would be even worse for global consumers. A shift from a geographically differentiated market to a non-differentiated market will ultimately produce a change in drug pricing that could lead to lower-end markets out of the picture, generating more societal losses overall.

B.

Innovation

Though it is very difficult to obtain empirical data on the effects of profits and patents on innovation, the strongest objections to pharmaceutical reimportation is that by lowering industry profits by eliminating differential pricing, pharmaceutical innovation will be detrimentally affected. If the revenues fall below the costs necessary to cover research and development, firms will not go into the drug-making business. Barfield and Groombridge argue, “Whatever the individual circumstances, the basic economic fact is that over the long haul if a firm is to survive the average costs across all units of production in all markets must be sufficient to cover the average total cost, including the sunk joint costs.”¹⁵⁸

In the economic model presented above, price differentiation enhances social good by providing more incentives to producers to innovate while reducing deadweight loss. As Figure 5 shows, the result of a reimportation scheme would be to reduce producer surplus and the associated incentives it generates for creation.

C.

Safety

The primary reason that MEDSA and other reimportation measures were not implemented was public safety. The FDA and pharmaceutical industry argued vehemently that the public would put at great risk if reimportation were allowed. Following the same reasoning as the PDMA, such fears are primarily based on the possibility that subpotent or adulterated goods would be allowed to enter the U.S. market. MEDSA attempts to address this by requiring sampling and testing of each shipment of reimported goods.¹⁵⁹ However, MEDSA relies on a scheme of self-reporting to achieve this goal. Though MEDSA requires suspension of

¹⁵⁷ *Id.* at 250.

¹⁵⁸ *Id.*

¹⁵⁹ MEDSA, *supra* note 1, at § 745(d)(6)(C) - (D).

importation if a particular importer is found to be shipping goods that are counterfeit or adulterated,¹⁶⁰ the already limited resources of customs in checking drug shipments could likely not be able to properly enforce such a suspension.

Though the costs of implementing and enforcing proper safety measures are unknown, it is clear that there is a tradeoff between the degree of reimportation and safety. For instance, MEDSA limited the countries from which drugs could be reimported in order to limit the sources of potentially unsafe drugs. However, at the same time this measure was criticized for limited the potential cost savings to consumers for drugs reimported from low-cost markets. Furthermore, the increase in quantity of reimported drugs would require an increase in administrative enforcement from the FDA and Customs officials to ensure safety of the drugs, cutting into any cost savings that might have been achieved.

D.

Future Issues: The Problem of Illegal Importation for Personal Use

The stories of trips to Mexico and Canada to obtain cheaper drugs are but part of the greater problem of frustrated individuals and groups who may potentially turn to illegal importation to alleviate the high cost of drugs. With the rise of internet sales of drugs from international sources, consumers will likely find that access to such drugs easier as time progresses. If such practices proliferate, they may render the PDMA and the entire reimportation debate obsolete by allowing Americans easy, though illegal, access to foreign drugs at lower prices.

1.

The Regulation of Pharmaceutical Imports

Currently, pharmaceutical importation is regulated through a number of sources. The FDCA prohibits the importation of unapproved, misbranded, or adulterated drugs.¹⁶¹ In addition, the PDMA imposes criminal sanctions for knowing violations of the reimportation ban.¹⁶² In response to the need of some patients to receive potentially life-saving drugs unavailable in the United States, the FDA has a personal importation policy that allows the exercise of enforcement discretion to allow importation of an unapproved prescription drug as long as: 1) the product is for less than 90 days of personal use; 2) the product is used to treat a serious condition with no available effective remedies in the United States; 3) there is no known advertising to U.S. residents by those distributing the product; 4) the product is not considered unreasonably risky; 5) the patient affirms in writing that the product is for personal use and provides the contact information of a U.S. doctor responsible for the treatment or provides evidence that the product is for continuation of treatment started abroad.¹⁶³

¹⁶⁰*Id.* at § 745(g).

Custom's officials enforce this regime by identifying parcels that may violate the importation bans and determining whether they should or should not remain in the country. FDA inspectors then notify the recipient of a potential violation, and allow for a response; if the response is inadequate, the package is returned to the sender. Sources report that two million packages containing foreign drugs for personal use enter the country each year.¹⁶⁴ Enforcement of drug importation regulations is difficult given the difficulty of inspection and the rise in internet sales.

2.

Online Pharmacies and International Drug Discount Programs

An important issue that is likely to gain prominence in the debate over the high cost of prescription drugs is the increasing availability of prescription drugs on the internet. According to some estimates, there are possibly 400 illegal internet sites that sell prescription drugs to Americans without a proper prescription.¹⁶⁵ Some online pharmacies, such as Drugstore.com, offer their low prices as an alternative to going across the border to obtain cheaper drugs.¹⁶⁶ In 2001, a Canadian internet company announced a venture to offer Canadian-priced prescription drugs to Americans through an on-line prescription exchange program.¹⁶⁷ Online pharmacies have caught the attention of lawmakers concerned with the safety of such drugs.¹⁶⁸ Though there are numerous regulations restricting the importation of drugs, many believe that they cannot effectively address the seriousness of the problem posed by importation through internet sites.¹⁶⁹ The main problem is that these sites can locate abroad where U.S. authorities do not have the power to attack them directly.¹⁷⁰ FDA's primary enforcement action of writing a cease and desist letter seems of little avail without possibility of actual punishment.¹⁷¹ Though the difficulty of regulating these sites is acknowledged, the U.S. is not completely powerless in enforcing its laws abroad. The Department of Justice is seeking the cooperation of other nations in the investigation and prosecution of computer crimes.¹⁷² Further, the government can work with U.S. credit card companies and financial institutions to disrupt the illegal sale of drugs on the web.¹⁷³

The other way that the U.S. can try to stop the flood of illicit prescription drugs is by curbing the entry

¹⁶⁴Conlan, *supra* note 60, at 32.

¹⁶⁵James G. Dickinson, *Illegal Internet Rx Sites Up to 400*, MED. MARKETING AND MEDIA, Nov. 1, 2001, at 36.

¹⁶⁶Peter Neupert, *Lower Drug Prices Can Be Found Online*, BUS. WEEK, Oct. 30, 2000.

¹⁶⁷William Langbein, *Web Company Offers Drugs in U.S. at Canadian Prices*, Yahoo News, Sep. 7, 2001, at <http://dailynews.yahoo.com/h/nm/20010907/hl/drugs.2.html>.

¹⁶⁸Some online pharmacies simply require the customer to fill out an online evaluation to obtain the drug. See Kai Wright, *Online Pharmacies Evading Regulation*, Salon.com, Apr. 17, 2000, at <http://www.salon.com/health/feature/2000/04/17/internet-pharmacy/>. More legitimate sites require that a doctor or pharmacist fax the prescription to the online service.

¹⁶⁹See, e.g., Wright, *supra* note 168.

¹⁷⁰The U.S. Department of Justice and State attorneys general have instituted a number of lawsuits against illegal online drug distribution within the U.S. See Statement of Ethan Posner, Deputy Associate Attorney General, U.S. Department of Justice, Before the Subcommittee on Oversight and Investigations, U.S. House of Representatives, May 25, 2000, *available at* <http://www.cybercrime.gov/posner.htm>; Wright, *supra* note 168.

¹⁷¹See *id.*

¹⁷²Statement of Ethan Posner, *supra* note 170.

¹⁷³*Id.*

and demand of such drugs. However, the rising number of illegal shipments will likely make searching and seizing the drugs almost impossible.¹⁷⁴ The U.S. Customs Service seized 10,000 packages in 1999 with illicit prescription drugs, a number four times greater than the previous year.¹⁷⁵ Perhaps the most troubling aspect of internet sales of prescription drugs is the lack of consumer awareness and concern that these drugs may be misbranded or adulterated.¹⁷⁶ Without better enforcement, monitoring, and education, more people in the United States will undoubtedly turn to such sites to buy cheaper prescription drugs from overseas sources.

V.

Solutions to the Prescription Drug Problem

Instead of a policy that attempts to eliminate price discrimination by allowing reimportation, the government should consider ways of providing prescription drugs for the uninsured elderly that do not jeopardize the profits needed as incentives for pharmaceutical research. The most widely discussed proposal for dealing with the prescription drug problem is to implement a prescription drug benefit as part of Medicare. However, a federally sponsored prescription drug subsidy, though better than a reimportation policy, is a crude way of dealing with the problem that would result in a large waste of resources. Rather, the government should look, somewhat counter intuitively, towards plans that *increase* price discrimination such that those without the ability to pay for drugs may obtain them for lower prices. A price discount plan for the uninsured elderly has the potential to increase access to drugs without encroaching on pharmaceutical profits. The following sections will describe the problems with a federally sponsored drug benefit and analyze potential policies for drug discounts for seniors.

A.

Federally-Sponsored Prescription Drug Benefit

Though proposals to implement a prescription drug benefit as part of Medicare failed in 1999, Congress is feeling strong pressure to revive the effort. Such a plan would make the federal government and taxpayers subsidize prescription drugs costs for the uninsured elderly on Medicare. This would undoubtedly be a very costly entitlement program, which is why Republicans are reluctant to approve of such a plan. A major

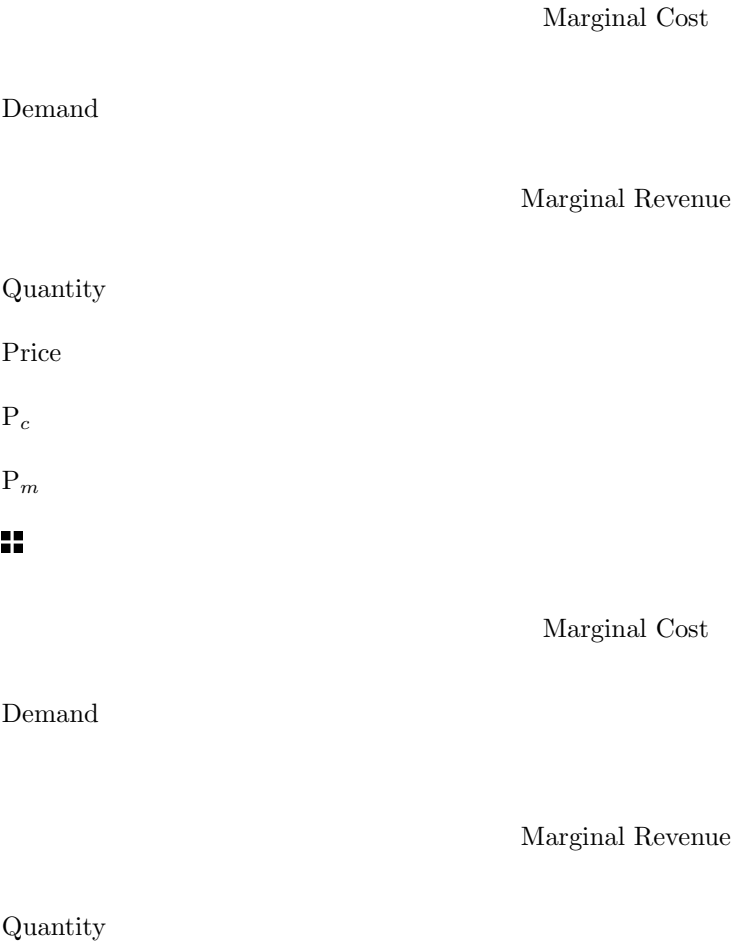
¹⁷⁴See Statement of Congressman John D. Dingell, Subcommittee on Oversight and Investigations Hearing on *Continuing Concerns over Imported Pharmaceuticals* (2001), available at <http://www.house.gov/commerce/democrats/press107st33.htm> (citing an FDA/Customs Service project in which of 16,000 parcels stopped for illegal importation of drugs, 14,000 were sent to their destinations without any review).

¹⁷⁵Wright, *supra* note 168.

¹⁷⁶See, e.g., *id.* (describing the lack of consumer complaints about online pharmacies as an indication of consumers' belief that such sites are safe and that prescription drugs can be obtained without a prescription).

drawback to the plan is inevitable leakage—some who do not truly need the discounts will be receiving them.¹⁷⁷ A more finely tuned plan could serve only the subset of Medicare recipients who do not have prescription drug coverage, although a process to determine who deserves coverage may be costly to administer. A second drawback is the political infeasibility of implementing such a plan. Though political pressure is mounting from the public and pharmaceutical industry to implement such a benefit, Congress has been extremely reluctant to pass a Medicare drug benefit due to its costs. An analysis of the potential impacts of a Medicare prescription drug benefit makes it clear why the pharmaceutical industry supports it, and why it may be also be a bad idea for policymakers. The following figure presents the theoretical result of a federal subsidy for those who cannot afford prescription drugs:

Figure 5: Medicare Prescription Drug Benefit



¹⁷⁷However, such a problem would be much more likely under a reimportation plan.

Price

P_c

P_m

Producer Surplus

Consumer Surplus

■

Deadweight Loss

Producer Surplus or Government Subsidy

Producer Surplus

Consumer Surplus

Deadweight Loss

Producer Surplus or Government Subsidy

As the figure shows, if the federal government subsidized prescription drugs for those who cannot currently afford them, it will eradicate the deadweight loss by supplying those who need prescription drugs. However, the government will be paying a price above many consumers' willingness to pay, resulting in a net societal loss of funds and a large subsidy to the pharmaceutical industry (above their monopoly profits in the current market). Therefore, a government-sponsored prescription drug benefit is likely to be of great cost with little

societal gain.¹⁷⁸ If, on the other hand, the government is able to obtain the additional drugs at low cost (near or slightly above marginal cost), then there would be no subsidy to the pharmaceutical industry and the plan would resemble the drug discount policies described below.

B.

Drug Discounts for Uninsured Elderly

1.

General Description

A plan that provides lower prices to uninsured seniors¹⁷⁹ yet keeps prices for the insured the same would allow access to necessary drugs for those who need them the most, while not jeopardizing the profits needed as incentive for pharmaceutical innovation. The benefits of such a policy over a reimportation or entitlement policy are manifest. If implemented well, a drug discount plan for uninsured elderly would allow drug manufacturers to reach out to consumers who could not otherwise be able to afford the drugs or are currently going across the border to find cheaper drugs, in theory rendering no loss of aggregate profits for the drug companies. Further, assuring safety of reimported drugs would not be an issue, and the complex infrastructure necessary to implement safety procedures such as those envisioned by MEDSA would not be necessary, making a discount plan cheaper to the government. Third, the price savings are going specifically to the people who need them—the elderly and uninsured—rather than the general public who might otherwise be able to afford these drugs. Furthermore, in a reimportation plan, it is unclear whether middlemen or the end consumer would be benefiting most from the price differentials, which would not be the case in a price discount policy.¹⁸⁰ The effects of such a policy are depicted as follows:

Figure 6: One-Tier Price Discounts for Uninsured Seniors



¹⁷⁸Though under the utilitarian theory, such a payment could be seen as societally beneficial as it provides producers with even greater incentives to innovate, such a subsidy is out of the norm for most industries and is probably goes beyond the point of beneficial incentive towards societal waste.

¹⁷⁹See Hussar, *supra* note 31, at 10.

¹⁸⁰It is possible that pharmacists would try to absorb some of the savings of a price discount program. However, the same possibility with a reimportation policy, which further introduced another level of middlemen, the parallel importers.

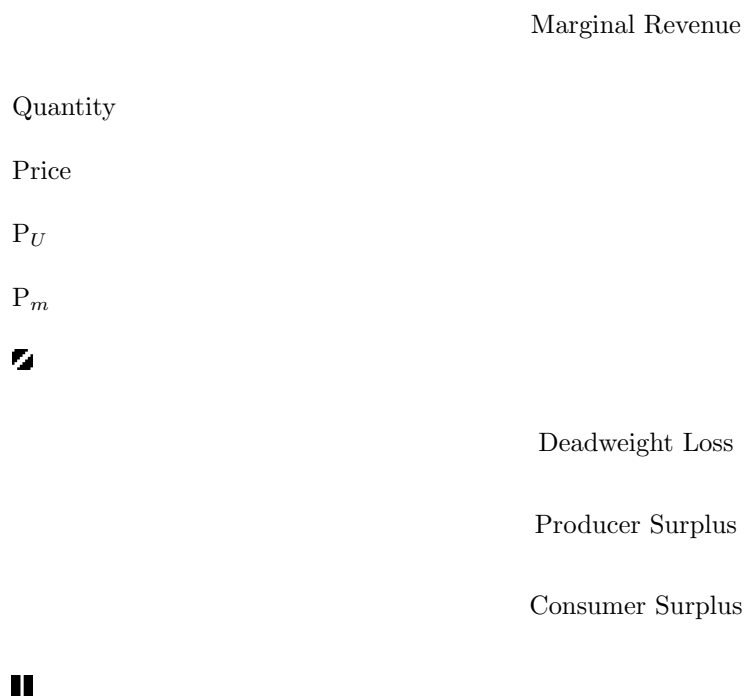


Figure 6: One-Tier Price Discounts for Uninsured Seniors



Deadweight Loss

Producer Surplus

Consumer Surplus

The diagram shows a hypothetical price discount program within a market of senior citizens in which the drug companies sell at two prices—the revenue-maximizing price for the insured seniors, and a discount price for those uninsured seniors that is slightly above the marginal cost of the drug. The diagram, though simplistic, shows that pharmaceutical industry gain in part from such a policy, consumers would certainly benefit, and deadweight loss would be reduced.

The primary objection that would undoubtedly be raised by the pharmaceutical industry is that the profits of the industry depend on sales to those very people who are uninsured. At the same time, those who are still subject to full prices but have difficulty paying will object on fairness grounds that they should have to pay full price. Empirical research should certainly be conducted to examine exactly who can afford drugs at what prices. A multi-tiered system of pricing or government subsidy could then be implemented:

Figure 7: Two-Tiered Price Discounts for Uninsured Seniors

Producer Surplus

Consumer Surplus

■

Deadweight Loss

Producer Surplus or Government Subsidy

Producer Surplus

Consumer Surplus

Deadweight Loss

Producer Surplus or Government Subsidy



P_m

P_U

Price

Marginal Cost



Demand

Marginal Revenue

Quantity

Though multi-tiered plan would be more complex to administer, the point is that the government or industry could potentially come up with a plan that makes drugs more available to consumers by reducing the inefficiencies of monopoly rather than cutting into pharmaceutical profits.

The primary drawbacks of the plan are leakage and arbitrage. The complexity in sorting and differentiating who pays what price will inevitably lead to a certain amount of leakage. However, an administrative system as developed as the Medicare system should be able to sort the different types of people and who deserves which price. The more difficult problem will be one of arbitrage. This could occur in two ways. First, a black market may develop for drugs that are sold at the low price. This is likely alleviated by the fact that these drugs may only be obtained with a doctor's prescription; still, there is a possibility that those without genuine needs will obtain prescriptions for drugs they can sell cheaply, or worse, those who need the drugs may sell them to instead to obtain a profit. A second way that arbitrage may occur is that many seniors that might otherwise be insured may decide not to become insured since they can obtain the lower prices if uninsured. A careful screening mechanism must be implemented, perhaps through Medicare, to ensure only those consumers who cannot afford private insurance can obtain the discounts. These mechanisms will likely add to the costs of such a program.

2.

Price Discount Proposals

The following proposals are different measures that might be taken to create a system of price discounts for uninsured seniors, some of which are currently being implemented or considered:

Price Controls

Price controls are seen by the pharmaceutical industry as a major threat to pharmaceutical profits. However, a narrowly tailored price control program that provides lower prices drugs to that proportion of the population that cannot afford them should not severely encroach upon pharmaceutical profits. The pharmaceutical industry would likely fight price controls tooth and nail. With the attitude of Americans and many politicians turning against the pharmaceutical industry, such a measure could possibly pass, though not likely in the near future.

Federal Drug Discount Cards

The Bush Administration has proposed a national prescription drug discount card program for the elderly in order to curb drug prices without federal appropriations by consolidating existing smaller pharmacy discount cards programs.¹⁸¹ A GAO report found that such a plan would create savings of only 10% to consumers, though supporters of a national card argued it would allow card users to be able to gain market power to bargain with large drug companies.¹⁸² An attempt to implement such a plan in 2001 failed due to legal challenges by the pharmacy industry that HHS did not have authority to establish such a plan.¹⁸³ Since then a bill has been proposed in the House to offer comprehensive pharmacy benefits to seniors, H.R. 3626.¹⁸⁴

Private Drug Discount Cards

In a clear response to public pressure, a number of major pharmaceutical companies have announced discount programs of their own for the poor and elderly.¹⁸⁵ In early 2002, Pfizer announced their "Share Card" which supplies the elderly a 30-day supply of any drug for \$15.¹⁸⁶ Eli Lilly followed with its discount card plan

¹⁸¹Amy Goldstein, *GAO Tests Value of Drug Discount Cards; Savings Less Than 10%, Study Shows*, WASH. POST, Jan. 4, 2002, at A25.

¹⁸²*Id.*

¹⁸³*Bush Resurrects Plan for Drug Discount Card*, Chain Drug Rev., Mar. 18, 2002, at 1.

¹⁸⁴*Id.*

¹⁸⁵Bill Brubaker, *Drugmakers Align to Offer Discount Card*, WASHINGTON POST, Apr. 10, 2002, at E01.

¹⁸⁶Adrian Michaels, *Pfizer Offers Cheap Drugs to US Elderly*, FT.COM, Jan. 15, 2002, at <http://news.ft.com/ft/gx.cgi/ftc?pagename=View&c=Article&cid=FT3DHHP2IWC>. The card does not apply to seniors living in states that have implemented drug assistance programs. *Id.*

allowing low-income elderly a month's supply of drugs for \$12.¹⁸⁷ In April of 2002, seven drug manufacturers¹⁸⁸ collaborated to offer the "Together Rx Card" in an attempt to streamline the various drug discount plans offered to low-income Medicare patients, offering over 150 drugs at 20%-40% discount.¹⁸⁹ Merck & Co., in a separate effort, has announced its plan to offer drugs at no cost to low-income households.¹⁹⁰ If these programs effectively provide drugs to the elderly persons who need them, it would be superior to a government-sponsored program, as the private sector would be absorbing the administrative costs of implementation. Though there are questions as to whether these plans can get drugs to all the people that need them, they are an important first step in recognizing that making drugs more available does not necessarily mean threatening the profits and innovativeness of the pharmaceutical industry.

Conclusion

The difficulty of high prescription drug prices remains an unsolved issue that will likely be of intense focus for state and federal politicians in the future.¹⁹¹ The need for political action is great—as public frustration reaches even higher levels, persons will be more likely to resort to illegal and unsafe means of obtaining drugs. The recent passage of MEDSA reflects the public and Congress' willingness to look to reimportation of U.S. manufactured drugs sold abroad as a possible solution to the problem. However, MEDSA's tenuous affect on consumer drug prices and consumer safety make it riddled with difficulties. Reimportation's theoretic results of eliminating geographic price discrimination will have detrimental results for society as a whole by reducing the incentive for drug manufacturers to innovate. Furthermore, a global pricing system for pharmaceuticals may create severe consumer losses, especially in developing countries. Lastly, reimportation of patented goods may be subject to legal challenge under current construction of the exhaustion of rights principle. Rather than considering reimportation, the government should implement a policy that provides lower-cost drugs to those who need them the most, the uninsured elderly. A policy of price discounts for uninsured elderly would improve the prescription drug situation without threatening the incentives for pharmaceutical innovation, and would lead to greater social benefits overall.

¹⁸⁷Ted Griffith & Lisa Smith, *Lilly to Offer Drug Discounts to Seniors*, N.Y. TIMES, Mar. 5, 2002, at <http://cbs.marketwatch.com/news/story.asp?guid={FCACAEA3-E6AE-4AA4-819E-7D04B9F5C93D}&symb=PFE&sid=3746&siteid=NYT&dist=NYT&osymb=PFE>

¹⁸⁸Abbott Laboratories Inc., AstraZeneca PLC, Aventis SA, Bristol-Myers Squibb Co., GlaxoSmithKline PLC, Johnson & Johnson and Novartis AG are offering the Share Card. Brubaker, *supra* note 185, at E01.

¹⁸⁹Brubaker, *supra* note 185, at E01.

¹⁹⁰*Id.*